

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: WAVE 4 CASES LISTED IN MOTION EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS' REPLY IN SUPPORT OF MOTION
TO EXCLUDE THE OPINIONS AND TESTIMONY OF SCOTT A. GUELCHER, PH.D.**

Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (collectively, “Ethicon”) submit this Reply in Support of their Motion to Exclude the Testimony and Opinions of Scott A. Guelcher, Ph.D. [Doc. [3664] (“Mot.”)] and Memorandum of Law in Support [Doc. [3667] (“Mem.”)], (collectively, “Motion”).

ARGUMENT

I. None of Dr. Guelcher’s Proposed Alternative Procedures or Materials Constitutes An Alternative Design to the Ethicon Mesh Products at Issue in this Litigation.

As Ethicon explained in its Motion, although Dr. Guelcher proposes a number of procedures and biological grafts as alternatives to the Ethicon mesh products at issue in this litigation, none of his proposals constitute alternative designs. *See* Motion at 2-4. Specifically, Ethicon showed (i) different *procedures*—like the Burch and needle suspension procedures advocated by Dr. Guelcher—cannot be said to represent alternative *designs* to Ethicon mesh products; and (ii) all of the biological grafts proposed by Dr. Guelcher have different implantation procedures and different functionality than Ethicon mesh products. *Id.* at 2-3.

A. Dr. Guelcher's proposed biological grafts are not alternative designs to Ethicon mesh products.

Plaintiffs failed to address Ethicon's arguments that biological grafts are not alternative designs to Ethicon's mesh products. *See* Resp. at 2-4. Thus, Plaintiffs implicitly concede that autografts are not medical devices, and that the implantation procedures and functional characteristics of all of Dr. Guelcher's proposed biological grafts are distinct from Ethicon mesh products. *See* Mot. at 3-4. Because Plaintiffs made no effort to show that biological grafts are proper alternative designs, the Court should preclude Dr. Guelcher from testifying about biological grafts at trial for the reasons stated in Ethicon's Motion.

B. This Court has already rejected Plaintiffs' argument that Dr. Guelcher's proposed alternative procedures and materials constitute an alternative design.

This Court has already rejected Plaintiffs' argument that Dr. Guelcher's proposed alternative procedures and materials constitute an alternative design. *Mullins v. Johnson & Johnson*, 2:12-cv-02952, 2017 WL 711766, at *2-3 & n.2 (S.D. W. Va. Feb. 23, 2017).

Plaintiffs make a feeble and disingenuous attempt to distinguish this ruling, claiming that this Court's ruling in *Mullins* "applies only to cases arising out of the state of West Virginia, and it leaves the ultimate determination of fact up to the jury." This is simply untrue.

As an initial matter, there is no basis to limit the Court's rulings regarding what constitutes an alternative design to West Virginia cases. Plaintiffs ignore the fact that the Court based its decision, in relevant part, on opinions issued by the Fourth and Fifth Circuits, not West Virginia state law. *See Mullins*, at *2-3 & n.2 (discussing *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) and *Theriot v. Danek Medical, Inc.*, 168 F.3d 253 (5th Cir. 1999)). Moreover, Plaintiffs failed to note the additional decisions to which Ethicon pointed in its brief, which are consistent with this Court's rulings. *See* Motion at 2-4 (citing, *inter alia*, *Hilaire v.*

DeWalt Indus. Tool Co., 54 F. Supp. 3d 223, 248 (E.D.N.Y. 2014) (New York case); *Schmidt v. C.R. Bard, Inc.*, 2013 U.S. Dist. LEXIS 101963, at *6 (D. Nev. July 22, 2013). Plaintiffs did not distinguish any of these cases, or articulate a principled legal basis to restrict this aspect of the Court's ruling to West Virginia.

Furthermore, this Court recently affirmed the broad applicability of its ruling in *Mullins* in excluding the alternative design opinions of Dr. Nathan Goodyear. *See* Mem. Op. & Order (Daubert Mot. re: Nathan W. Goodyear, M.D.), *In re: Ethicon, Inc.*, No. 2:12-md-02327 at 6 (S.D. W. Va. Mar. 29, 2017) [ECF 3540]. Specifically, the Court held that “alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists.” *Id.*

In addition, Plaintiffs appear to have misinterpreted the *Mullins* decision as it relates to Ethicon's Motion. Indeed, Plaintiff's response focuses on the Court's finding that the alternative design issue becomes a question of fact after plaintiffs satisfy their burden to present “evidence [sufficient] to identify a comparable product or design concept[.]” Resp. at 3. In so doing, however, Plaintiffs ignored the fact that this Court expressly ruled that “polypropylene suture is not an alternative, feasible design for the TVT device” at issue in that case, and that “plaintiffs must provide evidence of an alternative, feasible design for the product at issue,” not an alternative procedure. *Mullins*, at *3.

Finally, Plaintiffs claim that “Ethicon's reliance on *Theriot* . . . is completely misplaced[.]” because Dr. Guelcher “makes no *assumption* that all synthetic meshes are faulty[.]” but rather “he *finds fault* with using polypropylene-based meshes in this application.” Resp. at 3-4. Plaintiffs misunderstand not only Ethicon's argument, but also the opinions issued by the Fifth Circuit in *Theriot* and this Court in *Mullins*. These opinions stand for the proposition

that an alternative treatment options that completely avoid the use of the allegedly defective medical device—like the suture-based procedures Dr. Guelcher proposes—are not alternative designs for that device. *See Theriot*, 168 F.3d at 255; *Mullins*, 2017 WL 711766, at *2-3.¹ For this reason, the Court should preclude Dr. Guelcher from opining that suture-based procedures are alternative designs to Ethicon’s mesh products.

Thus, because none of the alternative procedures or materials proposed by Dr. Guelcher constitute alternative designs, the Court should preclude him from offering any alternative design opinions at trial.

II. Dr. Guelcher’s alternative design opinions are not the product of a reliable methodology.

As Ethicon explained in its Motion, the Fourth Circuit’s recent decision in *Nease* affirms that an expert cannot offer an opinion regarding alternative design without showing that the proposed alternative is actually safer and as effective as the product at issue through the use of reliable testing or scientific literature. *See* Motion at 4-6. Specifically, Ethicon showed that the Court should exclude Dr. Guelcher’s alternative design opinions because he failed to (i) test his proposed alternatives, and (ii) demonstrate that his proposed alternatives are safer and as effective as Ethicon mesh products in the treatment of SUI and POP. *See id.* at 4-8.

Although Plaintiffs do not dispute that Dr. Guelcher did not test his proposed alternatives, they argue that he based his opinions on his “experience in biomaterials, Ethicon’s internal

¹ In *Theriot*, the plaintiff argued that “other products that do not use pedicle screws should be considered as alternative designs,” rather than any pedicle screw. 168 F.3d at 255. Here, although Plaintiffs recognize that “[n]o mention of using other synthetic meshes is made in his report[,]” they appear to be oblivious of the fact that Dr. Guelcher proposed only suture-based procedures and biological grafts—neither of which is a proper alternative design to the Prolene mesh used in Ethicon mesh products. As courts across the country have repeatedly recognized, “an alternative design must not be an altogether essentially different product.” *Michael v. Wyeth, LLC*, No. 2:04-cv-0435, 2011 WL 2150112 at *11 (S.D. W. Va. 2011); *see also Talley*, 179 F.3d at 162 (upholding exclusion of expert opinion that spinal fixation screws were defective because spinal fusion procedures with the screws were not more effective than such procedures without screws); *Hilaire*, at 248 (“A plaintiff cannot satisfy his burden to propose a feasible alternative design by proposing that an entirely different product could have been used.”); *Schmidt v. C.R. Bard, Inc.*, 2013 U.S. Dist. LEXIS 101963, at *6 (D. Nev. July 22, 2013) (“[N]on-mesh repair is not an alternative design and does not meet Plaintiff’s burden to support [a design defect claim].”).

studies on mesh and Prolene specifically, all of the clinical literature about the foreign body response to polypropylene sutures and mesh, and many clinical papers comparing the use of biologics and other suture repairs to that of polypropylene mesh.” Resp. at 5. As discussed below and in Ethicon’s Motion, Plaintiffs’ argument is belied by Dr. Guelcher’s report and a substantial body of scientific literature.

A. Under *Nease*, an expert cannot offer alternative-design opinions at trial without test data or medical literature showing that the proposed alternatives are safer and at least as effective as the product at issue.

The Fourth Circuit’s recent decision in *Nease v. Ford Motor Co.* affirmed that an expert cannot offer an alternative-design opinion at trial absent test data or scientific literature showing that the proposed alternative is safer than the product at issue. 848 F.3d 219 (4th Cir. 2017). Specifically, Ethicon showed that Dr. Guelcher failed to ground his alternative-design opinions in testing or scientific literature demonstrating that his proposed alternatives are safer and at least as effective as Ethicon mesh products in treating SUI or POP. *See* Motion at 4-6.

Although Plaintiffs advance a number of arguments in an effort to distinguish *Nease*, their arguments are unavailing. For example, Plaintiffs’ claim that the Court should ignore the teachings of *Nease* because its discussion of *Daubert* issues is grounded in Fourth Circuit precedent, and testing is not an absolute requirement under *Daubert*. Resp. at 4-5. While Ethicon agrees with the Fourth Circuit’s affirmation that an “especially important factor for guiding a court in its reliability determination is whether a given theory has been tested,” (*Nease*, 848 F.3d at 231), Ethicon never argued that testing is an absolute precondition to the admissibility of expert testimony. *See* Motion at 4-8.

Rather, as the Motion clearly demonstrates, Ethicon argued that Dr. Guelcher’s alternative-design opinions are unreliable because he failed to show that his proposed alternatives are safer and as effective as Ethicon mesh products using reliable testing or scientific

literature. *See id.* Plaintiffs’ attempt to re-cast Ethicon’s position to fit their argument is a red herring.

Ultimately, nothing in Plaintiffs’ response demonstrates that Dr. Guelcher’s proposed alternatives are grounded in a reliable methodology. For this reason, the Court should exclude Dr. Guelcher’s opinions.

B. Neither Dr. Guelcher nor Plaintiffs identified any scientific literature showing that his proposed alternative procedures and materials are safer and at least as effective as Ethicon mesh products in treating SUI and POP.

Plaintiffs claim that Dr. Guelcher’s opinions regarding alternative designs are reliable because they are “completely grounded in the clinical and scientific literature,” and “based on measureable data with repeatable results from countless scientific experiments, decades of clinical usage and scientific study, and many papers that are recounted in his report.” Resp. at 5-6. But, as explained in Ethicon’s Motion, none of the materials to which he cites actually demonstrates that any of his proposed alternative designs are safer or as effective as Ethicon mesh products. *See* Motion at 6. Indeed, the only materials to which Dr. Guelcher cited regarding his proposed suture-based procedures address the foreign body reaction elicited by sutures and mesh—not whether suture-based surgical procedures like the Burch or needle suspension procedure are safer and as effective as Ethicon mesh products in treating SUI and POP. *See id.*

Tellingly, Plaintiffs failed to identify a single document showing that Dr. Guelcher’s proposed alternative designs are safer and as effective as Ethicon mesh products. *See* Resp. at 5-6. Even assuming *arguendo* that the “countless scientific experiments, decades of clinical usage and scientific study, and many papers that are recounted in his report” support Dr. Guelcher’s other opinions in this litigation, neither he nor Plaintiffs identified a single one that supports his alternative design opinions. The best Plaintiffs can muster is a vague reference to “over thirty papers on alternative design” that are purportedly listed in his reliance materials. *See id.*

In other words, Plaintiffs ask this Court to take their word for it that some unspecified sub-set of Dr. Guelcher's reliance materials—that he made no effort to identify—actually supports his opinions regarding suture-based procedures as alternatives to Ethicon mesh products. Neither Dr. Guelcher nor Plaintiffs can demonstrate that his opinions regarding suture-based procedures rest on a reliable foundation. *See Nease*, 848 F.3d at 234 (explaining that expert testimony “unsupported by any evidence such as test data or relevant literature in the field” should be excluded).

Turning to Dr. Guelcher's opinions regarding biological grafts as alternative designs, Ethicon explained in its Motion that while he identified three articles to support his opinions, they simply do not demonstrate that any of Dr. Guelcher's proposed alternatives is actually safer and at least as effective as Ethicon mesh products at treating SUI or POP.² Specifically, Ethicon discussed that the three articles on which Dr. Guelcher relies are neither recent nor long term. *See* Motion at 7-8. For this reason, Dr. Guelcher has absolutely no data or support regarding the long-term safety or efficacy of his proposed biological grafts as alternatives to Ethicon mesh products. Plaintiffs made no effort to rebut any of Ethicon's arguments, or identify any scientific support for Dr. Guelcher's opinions.

Dr. Guelcher's decision to rely on dated, short-term articles speaks volumes as to the dearth of scientific support for his opinions. This is particularly true given that, as discussed in Ethicon's Motion, Dr. Guelcher did not even acknowledge the substantial body of medical

² Plaintiffs assert that “while Ethicon also argues that Dr. Guelcher has not reviewed any papers on prolapse repair, a cursory review of his reliance list shows . . . the word prolapse . . . in the titles of fourteen different articles[.]” Resp. at 6. Plaintiffs appear to misunderstand Ethicon's argument. Ethicon did not argue that Dr. Guelcher “has not reviewed any papers on prolapse repair,” as Plaintiffs claim. Rather, Ethicon explained that Dr. Guelcher failed to identify scientific literature on which he relied showing that his proposed alternative designs were safer and as effective as Ethicon mesh products in treating of POP. *See* Motion at 7. Nothing in his report even suggests that Dr. Guelcher proposed a suture-based procedure to treat POP. Furthermore, as Ethicon discussed in its Motion, two of the three articles Dr. Guelcher identified as support for his biological graft proposals do not address POP devices in any way, while the third article did not actually report on complications or efficacy with respect to POP. *See id.* Plaintiff failed to rebut any of Ethicon's arguments.

literature that runs contrary to his opinions. *See* Motion at 8-10 & nn. 2-4 (discussing and citing studies). The lack of reliability underlying Dr. Guelcher's biological graft opinions is further demonstrated by the fact that the author of one of the articles on which Dr. Guelcher relies has explained that biological grafts do not offer better safety and efficacy rates than Ethicon mesh products. *See id.* at 8 (explaining that Dr. Brian Flynn concludes that biological grafts are not safer or more effective than Ethicon mesh products, and present additional risks not attendant to synthetic mesh).

C. Dr. Guelcher neither acknowledged nor accounted for the substantial body of scientific literature contradicting his alternative-design opinions.

In its Motion, Ethicon explained that a substantial body of scientific literature contradicts Dr. Guelcher's alternative-design opinions. *See* Motion at 8-10. Indeed, Ethicon identified a number of studies tending to rebut Dr. Guelcher's alternative-design opinions. *See id.* While an expert's opinions need not align with every piece of scientific literature to pass *Daubert* scrutiny, as this Court has recognized, if "the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *See Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *11 (S.D. W. Va. Sept. 29, 2014).

In their response, Plaintiffs make no effort to distinguish or dispute the findings of any of the literature identified by Ethicon. *See* Resp. at 6-7. Nor did Plaintiffs point to any specific literature that actually demonstrates that any of Dr. Guelcher's proposed alternatives is actually safer than and as effective as Ethicon mesh products in treating SUI or POP. *See id.*

For these reasons, as well as those identified in Ethicon's Motion, the Court should preclude Dr. Guelcher from offering opinions regarding alternative designs at trial.

CONCLUSION

For these reasons, as well as those discussed in Ethicon's Motion and Memorandum of Law in Support, Ethicon respectfully requests that the Court grant its Motion to Exclude the Opinions and Testimony of Dr. Scott Guelcher.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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